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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,194	05/30/2006	Jens Stougaard Jensen	09663.0066USWO	5997

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EXAMINER	
BUI PHUONG T	

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,194	JENSEN ET AL.	
	Examiner	Art Unit	
	Phuong T. Bui	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *2 and 6-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/27/06,4/4/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's restriction election filed August 27, 2008. Applicant elects Invention III and SEQ ID NO:8 with traverse. Applicant traverses primarily that once SEQ ID NO:8 is found allowable, all other polypeptides, nucleic acids and all methods claimed should be rejoined under Unity of Invention standard; the special technical feature that unifies the subject matter is that Nfr1, Nfr5 and Sym10 are three new species of Nod-factor binding elements; these three species share at least 60% sequence identity to each other; Nod Factor Binding Elements have not been identified in the art; and the method claims have all the limitations of claim 1. Applicant's traversals have been carefully considered but are deemed unpersuasive for the following reasons. With regard to the sequences, each sequence is a patentably distinct invention. Therefore, patentably distinct inventions (other polypeptides, nucleic acids, plants exhibiting particular phenotypes) are not rejoined upon allowability. However, process claims may be rejoined in accordance with *In re Ochiai*. While Nfr1, Nfr5 and Sym10 may be three new species of Nod-factor binding elements and have 60% sequence identity, this is not the standard for determining unity of invention. The specification discloses other Nod-factor binding elements that were known in the art at the time the invention was made (pp. 4-5); and there is no unity of invention rule requiring all sequences having at least 60% sequence identity be examined together. Accordingly, this restriction is maintained and made FINAL. Claims 1-29 are pending. Claims 1 and 3-5 (drawn to SEQ ID NO:8) are

examined. Claims 2 and 6-29 are drawn to nonelected inventions and are withdrawn from consideration.

Since SEQ ID NO:8 was first disclosed in provisional Application No. 60/484923, Applicant shall have benefit of priority of filing date July 3, 2003.

The status of parent Application No. 60/484923 should be updated in the first line of the specification.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See pp. 17 and 20, for example.

The sequences disclosed on p. 53 and Tables 1, 3, 11 and 12 fail to comply with 37 CFR 1.821-1.825. These sequences must have SEQ ID NO. identifiers.

Correction is required.

Claim Objections

3. Claims 1 and 3-5 are objected to because they recite non-elected sequences or are dependent on nonelected inventions.

Claims 1 and 4 are duplicate claims upon removal of nonelected inventions.

Claims 3 and 5 are duplicate claims upon removal of nonelected inventions.

Correction is required.

Information Disclosure Statement

4. Signed copies of Applicant's IDS filed February 27, 2006 and April 4, 2006 are attached. References which are not in proper citation format have not been considered. If Applicant wishes for these references to be considered, a new IDS listing these references in proper citation format must be submitted.

Claim Rejections - 35 USC § 112, second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 and 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it is unclear whether the citation in parentheses is intended to be a claim limitation. It does not appear to be an acronym.

In claim 1, it is unclear how "specific" is defined, and how one skilled in the art would be able to ascertain specific binding from other bindings. It is suggested that Applicant also add the function of "nodulating plants" as supported by the specification (p. 15).

In claim 1, it is suggested "identical" be amended to –sequence identity--, because it is unclear whether "identical" is determined by structure, function or other means.

In claim 1, it is unclear whether "functional fragment thereof" refers to the element or the polypeptide, and what the function is. See also claims 4 and 5.

Claim 4 does not further limit claim 1.

Claim 5(b) is interpreted to mean that that the functional fragment must contain SEQ ID NO:8, and "having" refers to both the NFR polypeptide and the functional fragment. If this is not Applicant's intention, the claim should be amended accordingly.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1 and 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:8, does not reasonably provide enablement for 60% identical to SEQ ID NO:8 or a functional fragment thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims directed to sequences that are 60% identical to SEQ ID NO:8 having "a specific Nod-factor binding property" and functional fragments thereof are not enabled for the following reasons. First of all, since it is unclear what "a specific Nod-factor binding property" is, one skilled in the art would not be able to determine from the population of sequences within the 60% identical genus has the asserted activity (see 112, 2nd paragraph rejection above). Further, the claims encompass unspecified base substitutions, deletions, additions, and/or combinations thereof while retaining function. Applicant provided no working example or guidance as to which amino acids can

tolerate mutations. The mutations are not limited to any particular domains or regions. The specification discloses some domains that are shared between different NFR polypeptides (p. 15) and alignment of 3 different NFR5 sequences (Table 1), but no guidance as to whether these domains or conserved regions will tolerate up to 40% mutations, or any mutations at all. The specification discloses mutants which cannot nodulate plants (p. 45) but it is unclear which mutations will retain the nodulation property. While one skilled in the art can readily make mutations, further guidance is required as to how inoperable embodiments can be predictably eliminated other than by random trial and error requiring undue experimentation.

Given the lack of working examples, lack of guidance and state of the art, one skilled in the art cannot make and use the claimed invention as commensurate in scope with the claims without undue experimentation.

9. Claims 1 and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant does not disclose a representative number of species as encompassed by these claims. Applicant does not adequately describe the population of sequences which have 60% identity to SEQ ID NO:8 and "specific Nod-factor binding property". The claims encompass other proteins, as well as mutants and allelic variants, and thus imply that structural variants exist in nature, yet no structural variant has been

disclosed. The claims also encompass sequences from other species. The implication is that there is a gene and a protein other than that disclosed which exists, in nature or synthetically made, but the structure thereof is not known. Based upon the disclosure of SEQ ID NO:8, it is unpredictable which other sequence structures within the 60% identity would also have "specific Nod-factor binding property". Thus, there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants, allelic variants and sequences from other plants and organisms, absent further guidance. Accordingly, there is lack of adequate description to inform a skilled artisan that Applicant was in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Stracke et al. (Nature, Vol. 417, June 27, 2002, pp. 959-962 (Applicant's IDS)) or Niebel et al. (MPMI, Vol. 10, No. 1, Jan 1997, pp. 132-134 (U)). The fragment size and "specific Nod-factor binding property" are not defined in the specification. Thus, the

claims read on any Nod-factor binding protein. Stracke and Niebel each teaches a "functional fragment" of a sequence which is at least 60% identical to SEQ ID NO:8 and has "specific Nod-factor binding property". Specifically, Stracke teaches plant receptor-like kinases isolated from lotus and pea which are required for bacterial and fungal symbiosis (Title). Niebel teaches two Nod-factor binding proteins NFBS2 and NFBS1 from *Medicago*. Accordingly, Stracke and Niebel each anticipated the claimed invention.

12. Claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Etzler et al. (USPN 6465716 (A)). The fragment size and "specific Nod-factor binding property" are not defined in the specification. Thus, the claims read on any Nod-factor binding protein. Etzler teaches a "functional fragment" of a sequence which is at least 60% identical to SEQ ID NO:8 and has "specific Nod-factor binding property". Specifically, Etzler teaches a Nod-factor binding lectin protein designated NBP46. Accordingly, Etzler anticipated the claimed invention.

Remarks

13. No claim is allowed. Claims 3 and 5 are free of the prior art.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong T. Bui/
Primary Examiner, Art Unit 1638
11/20/08